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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

AUG 23 1996

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

Oxyfluorfen. Magnitude of the Residue in Peaches (171-4(k). Case 2490.

MRID No. 44025401. DP Barcode: D227400. CBRS No. 17370.

FROM:

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Chemistry Pilot Review Team

Chemistry Branch II--Reregistration Support

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THRU:

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Chemistry Branch II--Reregistration Support

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TO:

Paula Deschamp, Section Head

Reregistration Section

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

Attached is the review of a residue trial study conducted on peaches as required under reregistration activities for oxyfluorfen. The data assessment has undergone secondary review in the branch and has been revised to reflect Agency policies. If you need additional information please advise.

CONCLUSIONS/RECOMMENDATIONS

See page 2.

cc: SF, List B File, RF, C. Eiden, Circ.

RDI: R. Perfetti 08/23/96

7509C: CM#2: Room 800: 305-7887: CAE 08/23/96

OXYFLUORFEN

Shaughnessy No. 111601; Case 2490

(CBRS No. 17370; DP Barcode D227400)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Data Call-In Notice, dated 9/93, to replace Craven Laboratories studies for oxyfluorfen, Rohm and Haas Company has submitted data pertaining to the magnitude of the residue in peaches (1996; MRID 44025401). The submitted data are evaluated for adequacy in fulfilling residue chemistry data requirements for the reregistration of oxyfluorfen.

The qualitative nature of the residue in plants is adequately understood based on acceptable metabolism studies with tomatoes, onions, and peaches. The terminal residue of concern is the parent, oxyfluorfen per se. The tolerance expression for oxyfluorfen has recently been amended (60 FR 62330, 12/6/95) to delete the metabolites of oxyfluorfen containing the diphenyl ether linkage. The established tolerances for plant and animal commodities [40 CFR §180.381 (a) and (b)] and processed commodities [40 CFR §185.4600] are now expressed in terms of oxyfluorfen per se [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene].

The Pesticide Analytical Manual (PAM) Vol. II lists two GLC/electron capture detector (ECD) methods, designated as Methods I and II, for the enforcement of tolerances for oxyfluorfen residues in/on plant and animal commodities, respectively. Both methods determine levels of oxyfluorfen and its reduced metabolites by a common moiety (as heptafluorobutyryl derivative of oxyfluorfen). The FDA Pestrak database (PAM Vol. I), dated 12/13/89, indicates that oxyfluorfen per se is completely recovered (>80%) using PAM Vol. I Multiresidue Protocols D and E (for non-fatty foods); recovery of oxyfluorfen metabolites containing a diphenyl ether linkage using Multiresidue Protocols A, D, and E is unlikely.

CONCLUSIONS AND RECOMMENDATIONS

- 1. The submitted data indicate that residues of oxyfluorfen per se were less than the LOQ (<0.01 ppm) in/on peaches harvested 90 or 134 days following a single dormant application of the 1.6 lb/gal EC formulation at 2.0 lb ai/A (1x the maximum seasonal rate) using ground equipment. These data adequately fulfill the requirements of the Data Call-In Notice, dated 9/93, to replace field trial data for peaches that were generated by Craven Laboratories.
- 2. With respect to tolerance reassessment for residues of oxyfluorfen per se in/on stone fruits, adequate field residue data from the current submission, the original petition (PP#4F3115), and from other recently reviewed submissions (CBRS No. 16313, DP Barcode D219897, S. Knizner, 1/2/96) are now available for the representative commodities cherries, peaches, and plums. CBRS concludes that the current tolerance level of 0.05 ppm for stone fruits is appropriate.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of peaches from the subject magnitude of the residue study were analyzed for residues of oxyfluorfen per se using a GC/ECD method, designated as Method TR 34-94-150 and entitled "Oxyfluorfen (Goal®) Crop Residue Analytical Method" by McKenzie Laboratories (State College, PA). This method is currently being proposed by the registrant as an enforcement method in conjunction with PP#3F4229/FAP#3H5674 (CBTS Nos. 16179 and 16180, DP Barcodes D218956 and D218957, W. Cutchin, 5/10/96); additional information pertaining to validation studies as well as an independent method validation trial and petition method validation by the Agency are required before the method can be considered adequate for enforcement purposes. A brief description of Method TR 34-94-150 follows. Residues in/on plant matrices are extracted with acetonitrile. The extract is then further purified by liquid-liquid partition, silica gel column chromatography, and basic alumina solid phase extraction. Oxyfluorfen residues are determined by GC using a Rtx-200 column and an electron capture detector. The method has a limit of detection (LOD) of 0.003 ppm and a limit of quantitation (LOQ) of 0.01 ppm. Sample calculations and chromatograms were provided.

The registrant provided concurrent method recovery data to demonstrate the adequacy of the analytical method. Oxyfluorfen recoveries, from untreated peaches fortified with oxyfluorfen at 0.01-0.50 ppm and then analyzed by Method TR 34-94-150, ranged from 70.0-93.7% (n = 20; average recovery = 85.6%; standard deviation = 7.2). These recovery data suggest that Method TR 34-94-150 is adequate for collection of residue data for oxyfluorfen from peaches.

7.2). These recovery data suggest that Method TR 34-94-150 is adequate for collection of residue data for oxyfluorfen from peaches.

Storage Stability Data

Samples of peaches from the subject magnitude of the residue study were frozen immediately after harvest. Samples were then shipped frozen either by ground carrier or by air freight to the analytical laboratory, McKenzie Laboratories, where the samples remained frozen until residue analysis. The total storage intervals between sample harvest and analysis were 156 and 327 days (5.1 and 10.7 months).

Adequate storage stability data are available to support the storage intervals and conditions of samples from the submitted field trials. Data submitted previously by the registrant indicate that fortified residues of oxyfluorfen *per se* are stable under frozen storage conditions for at least 3 years in/on peaches (CBRS No. 17259, DP Barcode D221585, C. Eiden, 7/2/96).

Magnitude of the Residue in Plants

Peaches

Established tolerance: A tolerance of 0.05 ppm has been established for residues of oxyfluorfen per se (60 FR 62330, 12/6/95) in/on stone fruits [40 CFR §180.381 (a)].

Registered use patterns: A REFS search conducted 7/31/96 identified three products registered to Rohm & Haas Company for use on peaches. The 1.6 and 2 lb/gal emulsifiable concentrate formulations (EC; Goal® 1.6E Herbicide, EPA Reg. No. 707-174; Goal® 2E Herbicide, EPA Reg. No. 707-145; and Goal® 2XL Herbicide, EPA Reg. No. 707-243) are registered for dormant applications to peaches at 0.5-2.0 lb ai/A. Applications are to be made as a directed ground spray in a minimum of 40 gal of water/A. A maximum seasonal rate of 2.0 lb ai/A is specified. Applications may be made alone or as a tank mix with other herbicides. Application after buds start to swell or when foliage or fruit are present is prohibited. The use of any treated plants for feed or forage or the feeding or grazing of any treated area is prohibited.

Discussion of the data: Rohm & Haas Company submitted data (1996; MRID 44025401) from two trials conducted in GA and PA depicting magnitude of the residue of oxyfluorfen in/on peaches. Mature peaches were harvested 90 or 134 days following a single dormant application of the 1.6 lb/gal EC formulation of oxyfluorfen at 2.0 lb ai/A using ground equipment (CO₂ backpack sprayer) in 40 gal of water/A mixed with surfactant. The protocol specified that applications were to be

made prior to budbreak; however, for the GA field trial, application was made during budbreak when ~35% bloom had occurred because of abnormally warm temperatures during the previous winter which resulted in premature budbreak. Peaches were bagged and frozen immediately after collection. Residues of oxyfluorfen were determined using Method TR 34-94-150, described above. Residues of oxyfluorfen were less than the LOQ (<0.01 ppm) in/on three treated and three untreated samples.

Geographic representation is adequate. The field trials were conducted in the test states specified in a Rohm and Haas proposal approved by the Agency (CBRS No. 12933, DP Barcode D197682, S. Funk, 12/21/93).

Summary of study: The submitted data indicate that residues of oxyfluorfen per se were less than the LOQ (<0.01 ppm) in/on peaches harvested 90 or 134 days following a single dormant application of the 1.6 lb/gal EC formulation at 2.0 lb ai/A (1x the maximum seasonal rate) using ground equipment. These data adequately fulfill the requirements of the Data Call-In Notice, dated 9/93, to replace field trial data for peaches that were generated by Craven Laboratories.

With respect to tolerance reassessment for residues of oxyfluorfen per se in/on stone fruits, adequate field residue data from the current submission, the original petition (PP#4F3115), and from other recently reviewed submissions (CBRS No. 16313, DP Barcode D219897, S. Knizner, 1/2/96) are now available for the representative commodities cherries, peaches, and plums. CBRS concludes that the current tolerance level of 0.05 ppm for stone fruits is adequate.

AGENCY MEMORANDA CITED IN THIS REVIEW

CBRS No.:

17259

DP Barcode:

D221585

Subject:

D221363

From:

Oxyfluorfen. Storage Stability on Various Crops: GLN 171-4(e) C. Eiden

To:

C. Eldell

Dated:

P. Deschamp

Daicu.

7/2/96

MRID(s):

43859801

CBRS Nos.:

16179 and 16180

DP Barcodes:

D218956 and D218957

Subject:

PP#3F4229/FAP#3H5674 Oxyfluorfen in or on Peanuts.

Amendment Dated 8/23/95 in Response to CBTS Review. Review

of Analytical Method and Residue Data. Rotational Crops Data

From:

W. Cutchin

To:

D. McCall

Dated:

5/10/96

MRID(s):

40567001 and 43756802 through 43756805

CBRS No.:

16313

DP Barcode:

D219897

Subject:

Oxyfluorfen. Magnitude of the Residue in Apple, Artichoke,

Avocado, Cherry, Fig, Kiwi, Olive and Pomegranate

From:

S. Knizner

To:

M. Wilhite

Dated:

1/2/96

MRID(s):

43794001 through 43794008

CBRS No.:

12933

DP Barcode:

D197682

Subject:

Oxyfluorfen (GOAL®) (List B, Chemical No. 111601, Case No.

2490). Registrant Response to 09/21/93 DCI for Replacement of

Craven Residue Chemistry Data.

From:

S. Funk

To:

B. Sidwell/M. Wilhite

Dated:

12/21/93

MRID(s):

None

MASTER RECORD IDENTIFICATION NUMBERS

The citation for the MRID document referred to in this review is presented below.

44025401 Martin, D.; Zhang, Q. (1996) Oxyfluorfen Residues in Peach: RAR 94-0117, 95-0196: Lab Project Number: 34-95-114: 34P-95-35A: 34P-95-51A. Unpublished study prepared by McKenzie Labs. and Rohm and Haas Co. 122 p.